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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/061,036	01/30/2002	Lloyd G. Simonson	06005.00001	8325
22908	7590	01/14/2004		
BANNER & WITCOFF, LTD. TEN SOUTH WACKER DRIVE SUITE 3000 CHICAGO, IL 60606			EXAMINER SWARTZ, RODNEY P	
			ART UNIT 1645	PAPER NUMBER 10

DATE MAILED: 01/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/061,036

Applicant(s)

SIMONSON, LLOYD G.

Examiner

Rodney P. Swartz, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 2october2003.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-29 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-29 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 9.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

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### **DETAILED ACTION**

1. Applicant's Response to Office Action, received 2 October 2003, paper #8, is acknowledged. Claims 1, 2, 5, 6, 7, 8, 9, 11, 12, 13, 14, 15, 16, and 19 have been amended. New claims 20-29 have been added.
2. Claims 1-29 are pending and under consideration.

### **Rejections Withdrawn**

3. The rejection of claim 2 under 35 U.S.C. 112, second paragraph, as being indefinite for patient bodily fluids, is withdrawn in light of the amendment of the claim.
4. The objection to claim 5 for informality is withdrawn in light of the claim amendment.
5. The rejection of claims 1-19 under 35 U.S.C. 112, second paragraph, as being indefinite for how labeling the antigen detects the presence of the antibody, is withdrawn in light of the amendment of the claims.

Applicant argues that the amendment of the claims obviates the rejection.

The examiner has considered applicant's argument, and finds it persuasive.

### **Rejections/Objections Maintained**

6. The rejection of claims 1-19 and, now newly added claims 20-29, under 35 U.S.C. 112, first paragraph, scope of enablement for detection of an antibody to a particular mycobacterium species utilizing an antigen from any/all other species of mycobacterium, is maintained.

Applicant argues that the amendment of the claims obviates the rejection.

The examiner has considered applicant's argument, but does not find it persuasive due to the language of the amendment of the claims. The newly amended claim 1 now recites a method for detecting the presence of  $\geq 1$  "predesignated" target antibody to "a" *M. tuberculosis* antigen in a fluid sample by contacting the sample with  $\geq 1$  membrane-bound *M. tuberculosis*

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antigen. The scope of the language of the amended portion claim does not restrict the membrane-bound antigens to those which would bind the "predesignated" antibody, but may be antigens which do not bind said antibody. The specification does not provide sufficient support for this possibility, nor define "predesignated" antibody.

Newly added claims 20-29 are included in this rejection because if claims 20-29 had originally been presented, they would have been included in the original rejection.

7. The objection to claim 6 for the informality of missing "of" between the words "mixture" and "two" is maintained for reasons of record.

Applicant argues that the amendment of the claim obviates the rejection. The examiner has considered applicant's argument, but does not find it persuasive because the listing of the claims does not indicate that claim 6 has been so amended.

### **Conclusion**

8. All claims are finally rejected.

9. Applicant's amendment necessitated the grounds of rejection for newly added claims 20-29 presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a)

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will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rodney P. Swartz, Ph.D., whose telephone number is (703) 308-4244.

The examiner can normally be reached on Monday through Thursday from 5:30 AM to 4:00 PM EST.

If attempts to reach the Examiner by telephone are unsuccessful, the examiner's supervisor, Lynette F. Smith, can be reached on (703)308-3909. The facsimile telephone number for the Art Unit Group is (703) 872-9306

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the group receptionist whose telephone number is (703)308-2035.



RODNEY P. SWARTZ, PH.D.  
PRIMARY EXAMINER  
Art Unit 1645

January 12, 2004